

## II. REMARKS

### Formal Matters

Claims 7-11, and 28-46 are pending after entry of the amendments set forth herein.

Claims 7-11 were examined and were rejected.

Claims 7, 9, and 11 are amended. The amendments to the claims have been made solely in the interest of expediting prosecution, and are not to be construed as acquiescence to any objection or rejection of any claim. Support for the amendments to claims 7, 9, and 11 is found in the claims as originally filed, and throughout the specification, in particular at the following exemplary locations: claims 7 and 11: paragraphs and 38-50; and Example 2; claim 9: paragraph 0040 . Accordingly, no new matter is added by these amendments.

Claims 28-46 are added. Support for new claims 28- 46 is found in the claims as originally filed, and throughout the specification, including the following exemplary locations: claims 28, 33, 39, and 44: paragraph 0053; claims 29-31 and 40-42: paragraph 0060; claims 32 and 43: paragraph 0025; claims 34 and 45: paragraph 0058; claims 35 and 46: paragraph 0072; claim 36: paragraph 0039; claim 37: paragraphs 0040 and 0050; and claim 38: paragraph 0050. Accordingly, no new matter is added by these new claims.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

### Rejection under 35 U.S.C. §112, first paragraph

Claims 7-11 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement.

The Office Action asserted that the claimed process steps are allegedly unclear to one of ordinary skill in the art. Accordingly, the Office Action alleges that the claimed invention is not enabled. The Office Action further alleges that the specification and working examples provide insufficient guidance and/or direction to clearly state applicant's claimed process steps regarding where to obtain the claimed preamble objective.

According to the MPEP §2164.01 an analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent

art to make and use the claimed invention. The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

Claims 7 and 11 are directed to methods for detecting the specific lysis of a target cell in a mixture of target cells. The methods involve contacting a lytic agent with both a first and at least a second fluorescently labeled target cell and detecting a reduction in fluorescence. Specification, paragraphs 38-50. Depending on the embodiment, either the plasma membrane or the cytosol of the target cells will be differentially labeled. Specification, paragraphs 38-50. The specification teaches how to incorporate a label into the plasma membrane and the cytosol of a target cell. Specification, paragraphs 52 – 57. The specification additionally teaches several different types of labels that may be used in accordance with the subject invention. Specification, paragraphs 58 – 59. Additionally, the specification teaches how to detect lysis of a target cell in a mixture of target cells. Specification, paragraphs 37 – 50. The specification further teaches the use of several different lytic agents. Specification, paragraph 60. Furthermore, the specification teaches how to determine if there has been a reduction in fluorescent label. Specification, paragraphs 71 – 73. Additionally, Example 2 sets forth working examples of the claimed invention. Accordingly, in view of the extensive teachings in the specification, those skilled in the art could practice the claimed invention without undue experimentation.

Nevertheless, and solely in order to expedite prosecution and advance the case to issuance, claims 7 and 11 are amended, as shown above.

Applicants submit that the rejection of claims 7-11 under 35 U.S.C. §112, first paragraph, has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejection under 35 U.S.C. §112, second paragraph

Claims 7-11 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action states that several steps of the subject invention are rendered vague and indefinite. Applicants respectfully disagree. Nevertheless, and solely in order to expedite prosecution and advance the case to issuance, claims 7 and 11 are amended, as shown above.

Applicants submit that the rejection of claims 7-11 under 35 U.S.C. §112, second paragraph, has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

### III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number GLAD-005DIV.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

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By:   
Paula A. Borden  
Registration No. 42,344

BOZICEVIC, FIELD & FRANCIS LLP  
1900 University Avenue, Suite 200  
East Palo Alto, CA 94303  
Telephone: (650) 327-3400  
Facsimile: (650) 327-3231